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BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte DOSUK D. LEE, CHRISTIAN REY,
MARIA AIOLOVA, and ALIASSGHAR TOFIGHI

Appeal 2008-2228
Application 09/284,297
Technology Center 1600

Decided: June 12, 2008

Before DEMETRA J. MILLS, ERIC GRIMES, and LORA M. GREEN, *Administrative Patent Judges*.

GREEN, *Administrative Patent Judge*.

DECISION ON APPEAL

This is a decision on appeal under 35 U.S.C. § 134 from the Examiner's final rejection of claims 40, 42, 43, 103, 111-120, 124-134,

138-143, 145, 148, 151, and 152.[1] We have jurisdiction under 35 U.S.C. § 6(b). Claims 40, 42, 43, 103 and 138 are the independent claims on appeal, and read as follows:

40. A method of preparing a bioceramic composition, comprising the following steps:

a) dry mixing powders of a calcium phosphate and a promoter;

b) prior to hydration of said dry powders prepared in step (a), pressing said dry powders to form a compressed object of a predetermined shape; and

c) hydrating said compressed object of step (b) to form a reaction product, said reaction product comprising a poorly crystalline apatitic calcium phosphate.

42. A composite material, comprising:

a strongly bioresorbable, poorly crystalline apatitic calcium phosphate having a calcium to phosphate ratio (Ca/P) of less than 1.5 in contact with a biocompatible supplemental material,

wherein said supplemental material is a bioresorbable material selected from the group consisting of silk, demineralized bone matrix, hyaluronic acid and derivatives thereof, polyorthoesters, polyglycolic acid, polylactic acid, and copolymers thereof, polyesters of ahydroxycarboxylic acids, poly(L-lactide) (PLLA), poly(D,L-lactide) (PDLLA), polyglycolide (PGA), poly(lactide-co-glycolide (PLGA), poly(D,L-lactide-co-trimethylene carbonate), and polyhydroxybutyrate (PHB), polyanhydrides, poly(anhydride-co-imide), and co-polymers thereof, and bioactive glass compositions;

a non-bioresorbable material selected from the group consisting of dextrans, polyethylene, polymethylmethacrylate (PMMA), carbon fibers, polyvinyl alcohol (PVA), poly(ethylene terephthalate)polyamide, bioglasses, and calcium phosphates;

a lubricant selected from the group consisting of silicone oil, polymer waxes, lipids, and fatty acids; or

a radiographic material; and

wherein said supplemental material is present in an amount effective to impart a characteristic selected from the group consisting of strength,

[1] Claims 121-123, 135-137, 146, 147, 149, 150, and 153 have been objected to as being dependent on a rejected base claim (Reply Br. 3).

resorption time, adherence, frictional characteristics, release kinetics, tensile strength, hardness, fracture toughness, elasticity, and imaging capability to said composite.

43. A bioceramic composition comprising:

a compressed powder object of a predetermined shape,

said compressed powder object comprising dry powders of a calcium phosphate and a promoter,

wherein said promoter is selected to promote conversion of said calcium phosphate into a strongly bioresorbable, poorly crystalline apatitic calcium phosphate.

103. A method for treating a bone defect comprising:

identifying a bone site for receiving an implant;

introducing a compressed powder object at the bone site, said compressed powder object comprising dry powders of a calcium phosphate and a promoter and having approximately the shape required for repair of the bone defect,

whereby said compressed powder object is converted *in vivo* upon hydration at the implantation site into a strongly bioresorbable poorly crystalline apatitic calcium phosphate.

138. A method of preparing a bioceramic implant composition, comprising:

mixing powders of a calcium phosphate and a promoter selected from calcium metaphosphate, dicalcium phosphate dihydrate, heptacalcium decaphosphate, calcium pyrophosphate dihydrate, poorly crystalline apatitic (PCA) calcium phosphate, calcium pyrophosphate, monetite, octacalcium phosphate, CaO, calcium acetate, H_3PO_4, and amorphous calcium phosphate in a hydrating medium to form a paste, said promoter selected to convert the mixed powders into a poorly crystalline apatitic calcium phosphate;

introducing said paste into a mold that approximates a desired implant shape; and allowing said paste to harden.

The Examiner relies on the following references:

Constantz ('971)	US 5,782,971	Jul. 21, 1998
Constantz ('028)	US 5,962,028	Oct. 5, 1999
Constantz ('162)	US 6,005,162	Dec. 21, 1999

We affirm-in-part.

DISCUSSION

Claims 43, 127-131, 133, and 134 stand rejected under 35 U.S.C. § 102(e) as being anticipated by Constantz '028.

Constantz '028 is cited for teaching a method of making a compressed powder object, wherein the reference uses calcium carbonate, a crystalline growth inhibitor, and a promoter, to which is added calcium phosphate as a dry powder, which is then mechanically mixed by dry mixing using rollers with or without added water (Ans. 4). The Examiner notes that because of the use of the transition phrase "comprising," the composition does not exclude a liquid (Ans. 3-4). The Examiner finds that the rollers create compression of the mixed materials during the mixing process (*id.* at 4). The Examiner finds further that the "instant compressed powder objects of poorly crystalline apatitic [calcium phosphate] would result, as the compositions are of less than 1.5 Ca/P (col. 4, line 61)," (*id.* at 4) which, according to the Examiner, is one of the criteria of a poorly crystalline apatitic (PCA) calcium phosphate (*id.*).

Appellants argue that the '028 patent "nowhere discloses the formation of a compressed powder object." (App. Br.[2] 11.) The '028

[2] All references to the Appeal Brief are to Appellants' Brief on Appeal, date stamped May 21, 2007.

patent, Appellants assert, "indicates that the dry ingredients are *mixed* using mills or rollers," failing "to teach or suggest that the dry ingredients are *compressed*." (*Id.*) Appellants argue that "'compressed'[3] powder objects result from pressing or squeezing powders together by applying force" (App. Br. 12), wherein the pressure may be applied by a handheld press or a hydraulic press (App. Br. 12, citing Spec. 61, ll. 19-27; 88, l. 20 to 89, l. 29). By contrast, Appellants argue, the dry ingredients of the '028 patent are simply dispersed, not compressed (App. Br. 12, citing Constantz '028, Col. 5, l. 66-col. 6, l. 9).

As to the Examiner's claim interpretation that claim 43 does not exclude water because of the use of the transition phrase "comprising," Appellants argue that the claim requires "*dry powders* of a calcium phosphate and a promoter." (Reply Br. 7).

It is axiomatic that in order for a reference to anticipate a claim, it must disclose every limitation of the claimed invention, either explicitly or inherently. *In re Schreiber*, 128 F.3d 1473, 1477 (Fed. Cir. 1997). We find that the Examiner has not demonstrated by a preponderance of the evidence that Constanz '028 anticipates the rejected claims, and the rejection is reversed.

We interpret the limitation of claim 43 (emphasis added) of "*a compressed powder object* of a predetermined shape, said compressed powder object comprising *dry powders of a calcium phosphate and a*

[3] Appellants rely on Random House Webster's Collegiate Dictionary 279 (1992) and McGraw Hill Dictionary of Scientific and Technical Terms 427 (5th ed. 1994) to support the asserted definition of "compressed." (App. Br. 12.)

promoter," as requiring that the dry powders first be compressed into an object of predetermined shape, before any addition of a hydration agent.

Using that interpretation, the claim excludes the addition of a liquid in the formation of the powder object. We recognize that during prosecution before the Office, claims are to be given their broadest reasonable interpretation consistent with the Specification as it would be interpreted by one of ordinary skill in the art. *In re American Academy of Science Tech Center*, 367 F.3d 1359, 1364 (Fed. Cir. 2004). Claim language, however, "should not [be] treated as meaningless." *Bicon, Inc. v. The Straumann Co.*, 441 F.3d 945, 951 (Fed. Cir. 2006). The Examiner's interpretation reads the limitation of "dry powders of a calcium phosphate and a promoter" out of the claim.

We also interpret the term "compressed" as used in the relevant claims as requiring pressure in the formation of the object, such that an object of a defined shape is formed. That interpretation is consistent with the Specification, which teaches solid PCA calcium phosphate compositions, in which the solid is prepared by compressing the unreacted precursors of the PCA material (Spec. 61, ll. 4-6). According to the Specification,

> compressing the unreacted precursors of the PCA material produces the pre hardened pellet. The first component is an amorphous calcium phosphate. The second component is the promoter. The preferred promoter is dicalcium phosphate dihydrate (DCPD). . . . The two components are compressed and molded into the desired shape by any suitable method. Preferred embodiments of compression and molding include hand-held presses and hydraulic presses as described in examples 1 and 2. The pressure of the compression is dependent on what characteristics are desirable for the pellet. For instance, lower pressures are favorable for a pellet that is quickly resorbable. Other methods of pellet fabrication known

> in the pharmaceutical industry are also acceptable. The compressed object of desired shape most preferably reacts endothermically at 37°C in vivo to form PCA calcium phosphate.

(*Id.* at ll. 18-30.)

Constantz '028 teaches combining the dry components by mixing, such as by ball milling, Brabender mixing, rolling between rollers and a flexible container, wherein the mixing is for a relatively short time until a uniform dispersal of ingredients is obtained (Constantz '028, col. 5 l. 66-col. 6 l. 9). During the mixing or milling, the walls of the mixing container may be periodically scraped to promote a uniform product (Constantz '028, col. 8 ll. 48-50). Thus, Constantz '029 teaches only mixing to obtain a uniform dispersion, and not compression of the dry ingredients such that the dry ingredients assume a defined shape.

The Examiner asserts that "compression," given its broadest reasonable interpretation, encompasses applying pressure via syringe, kneading, shaping, and forming (Ans. 9). As noted by Appellants, however, pressure is not applied by a syringe, kneading, shaping, and forming until after a fluid is added, and is not performed on the dry powders (*see* Constantz '028, col. 6, ll. 28-36).

As to claim 127, claim 127 is dependent on claim 43 and adds the limitation that the "object further comprises a hydration medium to hydrate the object." Thus, we interpret claim 127 as adding a hydration medium to the compressed powder object of claim 43. As Constantz '028 does not teach the compressed powder object of claim 43, and as the Examiner does not provide any evidence or scientific argument that adding hydration medium to the dispersion of dry ingredients of Constantz '028 results in the

same composition as adding hydration medium to the compressed object of claim 43, the rejection is reversed as to claim 127 as well.

Claims 42, 43, 126-134, 151, and 152 stand rejected under 35 U.S.C. § 102(e) as being anticipated by Constantz '971.

Constantz '971 is cited for teaching mixing of dry powders, including a calcium phosphate (which the Examiner notes reads on the instant supplemental ingredient), a promoter, calcium carbonate, and amorphous calcium phosphate (ACP), and pressing, without the addition of liquid (Ans. 4-5). Constantz '971 is also cited for teaching a Ca/P ratio between 1.1 and 2 (*id.* at 5). The Examiner also notes that the use of the transition phrase "comprising" does not exclude the use of a hydration material (Ans. 10).

As to independent claim 42, Appellants argue that the '971 patent fails to teach or suggest any of the supplemental materials required by that claim (App. Br. 19). Appellants assert that:

> With respect to independent claim 42, the Examiner states that the '971 patent describes the dry mixing of powders of a calcium phosphate, which is considered as "the instant supplemental material," a calcium carbonate, and an amorphous calcium phosphate (ACP; Examiner's Answer, p. 5). The Examiner fails, though, to indicate where the '971 patent teaches or suggests a composition having the combination of elements recited in present independent claim 42: a *PCA calcium phosphate* and a calcium phosphate as the supplemental material. The '971 patent only describes the combination of amorphous calcium phosphate (ACP) with additional sources of calcium, including calcium phosphates (namely tetracalcium phosphate, tricalcium phosphate, dicalcium phosphate and its dihydrate, and monocalcium phosphate and its monohydrate; see, e.g., col. 4, lines 12-22).

> Nowhere does the '971 patent teach or suggest the combination of a PCA calcium phosphate with a second calcium phosphate.

(Reply Br. 8-9.)

Claim 42 requires poorly crystalline apatitic (PCA) calcium phosphate having a calcium to phosphate ratio of less than 1.5, in contact with a biocompatible supplemental material, such as provided by calcium phosphates. Constantz '971 teaches flowable calcium phosphate compositions comprising amorphous calcium phosphate and an additional calcium source, such as one additional calcium phosphate source, wherein the composition sets into an apatitic product with a crystallinity that approximates the crystallinity of bone (Constantz '971 col. 2, ll. 41-52). Thus, once the composition sets, it comprises a combination of a PCA calcium phosphate with a second calcium phosphate. Thus, we find that Constantz '971 anticipates the subject matter of claim 42. As Appellants do not argue dependent claim 152 separately from claim 42, it falls with the independent claim. 37 C.F.R. § 41.37(c)(1)(vii).

As to independent claim 43, Appellants argue that the '971 patent does not teach or suggest a compressed powder object nor a method of manufacturing a compressed powder object (App. Br. 17). Specifically, Appellants assert that the '971 patent "discloses the mixing of dry ingredients followed by hydration with a lubricant, specifically to produce a *flowable* composition . . ., not a *compressed* powder object" as required by independent claim 43.

As has been already discussed, we interpret the limitation of claim 43 of "a compressed powder object of a predetermined shape, said compressed powder object comprising dry powders of a calcium phosphate and a

promoter," as requiring that the dry powders first be compressed into an object of predetermined shape, before any addition of a hydration agent. Constantz '971 teaches mixing of the dry ingredients, to which is then added a liquid component to produce a flowable composition (Constantz '971 col. 6, ll. 12-20). Thus, Constantz '971 does not teach compression of the dry ingredients such that the dry ingredients assume a defined shape. The rejection is therefore reversed as to claim 43 and the claims dependent thereon, *i.e.*, claims 126-134 and 151.

Claims 40, 43, 103, 111-120, 124-134, 138-143, 145, 148, 151, and 152 stand rejected under 35 U.S.C. § 103(a) as being obvious over the combination of Constantz '971 with Constantz '162.

Constantz '971 is relied upon as above. According to the Examiner, the '971 patent "uses the instant components, mixed as powders, with lubricant physiologic fluids to provide wet mixing, or added after mixing, followed by compression." (Ans. 6.) As to claim 40, the Examiner notes that Constantz '971 does not clearly recite "compression followed by hydration," but asserts that "the reiteration in the patent of dry mixing, with wet ingredients then added, followed by shaping, molding, packing & the like . . . would make it evident to the artisan that [sic] the process of the instant compression." (*Id.*)

As to claim 103, the Examiner notes that the claim "is not clearly recited" by Constantz '971, but asserts that "if one reads the compressed powder object to permit of liquid, the Constantz lubricants, as permitted under the comprising guise, then the method of 103 also becomes obvious,

as filling bone voids with the composition is a method of treating a bone defect." (Ans. 6.)

As to claim 138, the Examiner finds that Constantz '971 does not point to introducing the calcium phosphate and a promoter with lubricant into a mold, but asserts "a prosthetic implant is suggested . . ., thus one would recognize formation of such a product would be done using a mold." (Ans. 6.)

According to the Examiner, Constantz '971 does not discuss the instantly claimed supplemental components, but the Examiner asserts that these "components are optional additives well known to be used for their intended purposes & applied to optimize the benefits of utilization of the CaP materials, & are given no patentable weight." (*Id.* at 7.) The Examiner also relies on Constantz '162 to show the optional components (*id.*).

The Examiner concludes:

> It would have been obvious to a person of ordinary skill in the art at the time the invention was made desiring to utilize an bone defect composition to prepare one of Constantz, with modification to use any of art recognized means to improve setting, dependent upon desired healing characteristics, shown by Constantz, 6005162. Motivation to use a specific additive is shown to be a function of desired effects, & art recognized, by Constantz, 6005162 and adjuvants and exact ratios and amounts effects, such as control of setting time, strength, pharmacological effects, compatability, resorbability & stability.
>
> The amounts and proportions & forms of each ingredient are result effective parameters chosen to obtain the desired effects. It would be obvious to vary the form of each ingredient to optimize the effect desired, such as enhanced setting time, strength, resorption, depending upon the particular parameter of interest, with consideration of compatibility of components with each other & with physiological tissue & fluids.

(Ans. 8-9.)

"In rejecting claims under 35 U.S.C. § 103, the examiner bears the initial burden of presenting a prima facie case of obviousness. Only if that burden is met, does the burden of coming forward with evidence or argument shift to the applicant." *In re Rijckaert*, 9 F.3d 1531, 1532 (Fed. Cir. 1993) (citations omitted). In order to determine whether a prima facie case of obviousness has been established, we considered the factors set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 17 (1996): (1) the scope and content of the prior art; (2) the differences between the prior art and the claims at issue; (3) the level of ordinary skill in the relevant art; and (4) objective evidence of nonobviousness, if present.

As to independent claims 40 and 43, and the claims dependent thereon, Appellants argue that claims 40 and 43 require the formation of a dry, compressed powder object, and that limitation is not taught by either of Constantz '971 or Constantz '162 (App. Br. 27). We agree for the reasons set forth above with regard to Constantz '971, and as Constantz '162 does not remedy the deficiencies of Constantz '971, the rejection is reversed as to claims 40 and 43, and the claims dependent thereon, *i.e.*, claims 111-120, 124-134 and 151. As claim 103 also requires a compressed powder object comprising dry powders of a calcium phosphate and a promoter, the rejection is reversed as to that claim as well.

As to claim 138, Appellants argue that "the '971 patent fails to teach or suggest the preparation of a bioceramic implant composition by introducing a calcium phosphate paste to a mold that approximates a desired implant shape." (App. Br. 30.) According to Appellants, the "'971 patent merely discloses the use of a mold or compression die for preparing a

hardened calcium phosphate solely for the purpose of determining the compression strength of the hardened calcium phosphate."[4] (*Id.*)

Claim 138 requires the steps of mixing powders of a calcium phosphate and a promoter in a hydrating medium to form a paste, said promoter selected to convert the mixed powders into a poorly crystalline apatitic calcium phosphate, and introducing said paste into a mold that approximates a desired implant shape; and allowing said paste to harden. The preamble recites method of preparing a bioceramic implant composition, but we conclude that is merely a statement of intended use, and not a patentable limitation.

Constantz '971 teaches a calcium phosphate paste comprising a calcium phosphate and a promoter (*see, e.g.*, Constantz '971 col. 4, ll. 12-22), and teaches the use of a physiologically acceptable lubricant to form a flowable paste like composition (*see id.* col. 2, ll. 44-49). Teflon mold rings are then filled with the paste like composition, and the composition is allowed to harden, that is, the composition is allowed to set (col. 7, l. 57-col. 8, l. 15). Thus, Constantz '971 teaches the steps of claim 138. As to the limitation that the paste is introduced into a mold that approximates a desired implant shape, Appellants have not presented scientific argument or evidence as to why the shapes provided by the Teflon mold rings of Constantz '971 could not be used as an implant.

Thus, we affirm the rejection as to claim 138 and the claims dependent thereon, *i.e.*, claims 139-143, 145, and 148.

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[4] Appellants note further that the '162 patent also discloses the use of a mold or compression die for preparing a hardened calcium phosphate for the purpose of determining the compression strength of the hardened calcium phosphate (App. Br. 31).

CONCLUSION

In summary, the rejection of claims 43, 127-131, 133, and 134 under 35 U.S.C. § 102(e) as being anticipated by Constantz '028, is reversed as to all of the rejected claims;

the rejection of claims 42, 43, 126-134, 151, and 152 under 35 U.S.C. § 102(e) as being anticipated by Constantz '971, is reversed as to claims 42 and 152, but affirmed as to claims 43, 126-134, and 151; and

the rejection of claims 40, 43, 103, 111-120, 124-134, 138-143, 145, 148, 151, and 152 under 35 U.S.C. § 103(a) as being obvious over the combination of Constantz '971 with Constantz '162 is reversed as to claims 40, 43, 103, 111-120, 124-134 and 151, but affirmed as to claims 138-143, 145, and 148.

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a)(1)(iv).

AFFIRMED-IN-PART

cdc

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